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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/678,957	10/03/2003	Wouter Bernard Veldhuis	2183-6141US	7282

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EXAMINER	
SEHARASEYON, JEGATHEESAN	
ART UNIT	**PAPER NUMBER**
1647	

DATE MAILED: 12/01/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/678,957	VELDHUIS ET AL.	
	Examiner	Art Unit	
	Jegatheesan Seharaseyon, Ph.D	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 October 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11 and 15-24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11 and 15-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *10/14/2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. This Office Action is in response Applicants response filed 10/14/2005. Claims 1, 9-11 and 15 have been amended. Claims 22-24 have been added. Claims 12-14 are cancelled. Thus, claims 1-11 and 15-24 are pending and is the subject of this action.

2. The text of those sections of Title 35, U. S. Code not included in this action can be found in a prior Office action.

3. The Office acknowledges the submission of modified figures. Figures 4, 8 and 10 have been revised.

4. The Office acknowledges the submission of IDS dated 10/14/2005.

5. The rejections pertaining to claims 12-14 are withdrawn because Applicants have cancelled.

Claim Rejections - 35 USC § 112, first paragraph, scope of enablement maintained

6. The rejection of claims 1-11, 15-21 and 22-24 (newly added) under 35 U.S.C 112, first paragraph, as lacking enablement is maintained for reasons of record in the Office Action dated 6/7/2005 (see pages 3-7).

The specification while enabling for a method of administering full-length IFN-β to reduce or treat tissue damage, cell death, inflammation and improving blood flow as a result of hypoxia/ischemia, related blood flow resistance, including treating cell death as a result of hypoxia/ischemia does not reasonably provide enablement for a method of administering functional parts, derivatives, and/or analogues of all type-I Interferons (IFN type-I) to treat or prevent tissue damage, hypoxia/ischemia, related blood flow resistance, including treating cell death as a result of hypoxia/ischemia.

Applicants' arguments have been fully considered but are not found to be persuasive. Specifically with respect to functional part, derivative and/or analogue of IFN type-I, Applicants argue that interferons are long-studied group of proteins. It is asserted that one of ordinary skill in the art is well aware of functional parts, suitable derivatives and analogues of IFN type-I. Furthermore, claims as written also read on any derivatives and/or analogues of IFN type-I irrespective of its functional status. Applicants on pages 7-8 of response filed 10/14/2005 discuss extensively about interferons and its derivatives claiming that one of ordinary skill in the art can rely on the large body of interferon art to produce many different derivatives or analogues of IFN type-I. While it is true that there exists substantial information in the art about different IFN type-I and its derivatives, there is no teaching in the art nor have the Applicants provided the identity of the "functional part" of IFN type-I that is responsible for reduction of post-ischemic damage activity. Applicants also argue that because all IFN type-I's share a common receptor through which their effects are mediated, not only is the disclosure enabling for IFN-β, but also for all IFN type-I. Although, the various IFN type-I's share a common receptor there is no evidence to suggest that they also provide the same therapeutic outcomes. Therefore, a person of ordinary skill in the art would not know how to make the invention as claimed and would require undue experimentation. While making derivatives and analogues of IFN type-I (including alfacon-1) may be well known to one of skilled in the art, making derivatives, analogues and functional part of IFN type-I that are capable of reducing post-ischemic damage activity are beyond the capabilities of those skilled in the art. Furthermore, Applicants have only presented a

single working example of using IFN-β (see page 19, paragraph [0066] and page 22, paragraph [0082]) without providing any direction or guidance to identify the functional parts, derivatives, and/or analogues of IFN-β to treat or reduce hypoxia/ischemia and the effects associated such as cellular damage and inflammation. Therefore, due to breadth of claims regarding functional part, derivative and/or analogue of IFN type-I, as well as the lack of guidance and working examples of derivative or analogue of IFN type-I and the lack of predictability of the activities resulting from the changes to IFN type-I, the examiner maintains that undue experimentation is required to practice the claimed invention.

Applicants also contend that amendments to claims 1, 9-11 and 15 with respect to the administration of dose are sufficient to overcome the pending rejection (see page 8 of response). However, the "therapeutically relevant" doses not provide any guidance for the administration of IFN type-I needed for example, in reducing cellular damage or inflammation due hypoxia and/or ischemia. Thus, in the absence of guidance, working examples and the breath of claims the pending rejections of record are maintained. Amending the claims to recite to read effective amount for treatment may over come the enablement rejection.

In addition, claim 11 remains rejected because the claims are drawn to "preventing cell death". Applicants' amendment is inadequate to overcome the rejection of record. Namely, Applicants have shown that IFN-β (a type-I) can decrease lesions following hypoxia/ischemia, but do not provide evidence of totally preventing cell death. Furthermore, there is no evidence in the literature of any treatment that can totally

prevent cell death following hypoxia/ischemia. Therefore, the rejection of record is maintained.

Claim Rejections - 35 USC § 112,1st paragraph, written description, maintained.

7. The rejection of claims 1-11, 15-21 and 22-24 (newly added) under 35 U.S.C 112, first paragraph, as failing to comply with the written description requirement is maintained for reasons of record in the Office Action dated 6/7/2005 (see pages 7-9).

Applicants argue that the specification provides adequate written description for a method of administering functional parts, derivatives, and/or analogues of IFN type-I to treat or prevent hypoxia/ischemia, related blood flow resistance, on page 9 of the response filed 10/14/2005. In addition, Applicants contend that structures of the claimed compounds are not required. Further, Applicants site MPEP 2163(a)(ii) to support their assertion. Applicants' arguments have been fully considered, but are not found to be persuasive. Contrary to Applicants' assertion, MPEP 2163(a)(ii) states that "the written description requirement for a claimed genus may be satisfied by... functional characteristics coupled with a known or disclosed correlation between function and structure... sufficient to show the applicant was in possession of the invention." However, there is no correlation between IFN type-I structure (functional part) administration and decrease in cellular damage or inflammation following hypoxia/ischemia that has been demonstrated by the instant disclosure or the interferon art. For example, MPEP 2163 1(A) states "The claimed invention as a whole may not be adequately described where an invention is described solely in terms of a method of its making coupled with its function and there is no described or art-recognized correlation

or relationship between the structure of the invention and its function. A biomolecule sequence described only by a functional characteristic, without any known or disclosed correlation between that function and the structure of the sequence, normally is not a sufficient identifying characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence". In the instant, Applicants have not demonstrated a correlation between that function and the structure of the sequence of IFN type-I. Therefore, rejection of record as claims lack in written description is maintained.

Claim Rejections - 35 USC § 112, 2nd paragraph, withdrawn.

7. The rejection of claims 1-11 and 15-21 under 35 U.S.C 112, second paragraph, as being incomplete for omitting essential steps or as being indefinite is withdrawn because Applicants arguments are deemed to be persuasive.

Claim Rejections - 35 USC § 103, maintained

8. The rejection of claims 1-11, 15-21 and 22-24 (newly added) under 35 U.S.C 103(a) as being obvious over Wee Yong et al. (1998) in view of Boyle et al. (1996) and Saikumar et al. (1998) is maintained for reasons of record in the Office Action dated 3/31/2005 (see pages 9-11).

Applicants appear to argue that even if one would decide that an anti-inflammatory property is an essential quality for a method for the treatment H/I related blood flow resistance, one's choice would not likely be interferon. Applicants contend that the mere fact that a compound has an anti-inflammatory effect does not make it suitable for a method on invention. Applicant's arguments do not comply with 37

CFR 1.111(c) because they do not clearly point out the patentable novelty which he or she thinks the claims present in view of the state of the art disclosed by the references cited or the objections made. Further, they do not show how the amendments avoid such references or objections.

Applicants' arguments have been fully considered but are not found to be persuasive. However, Applicants have not indicated why one of skilled in the art cannot combine the art of record. In addition, Applicants have not provided any evidence to indicate that why one cannot combine art provided to arrive at the instant invention in light of Wee Yong et al.'s teachings, which indicate that IFN-β (a type-I IFN) has known anti-inflammatory properties and Boyle et al.'s recognition that hypoxia/ischemia related injuries are proinflammatory processes. The art provided by the Office taught the motivation and the rationale for the expectation of success associated with it. It is noted "only a reason, suggestion or motivation need appear in the cited prior art in order to combine references under 35 U.S.C. 103. *Pro Mold Tool Col. v. Great Lakes Plastics, Inc., 75 F.3d 1568, 1573, 37 USPQ2d 1626, 1629 (Fed. Cir. 1996)".* Furthermore, Applicants citing of administration of Enlimolab studies (Stroke (2003) and Neurology(2001) articles) teaching away from the instant invention is not found to be persuasive because they did not use type-I IFN. Therefore claims 1-11, 15-21 and 22-24 (newly added) remain rejected as being obvious over Wee Yong et al. (1998) in view of Boyle et al. (1996) and Saikumar et al. (1998).

Claim Rejections - 35 USC § 102, maintained

9. The rejection of claims 1-11, 15-21 and 22-24 (newly added) under 35 U.S.C 102(b) as being anticipated by Sano et al. (EP 0797998 A1) is maintained for reasons of record in the Office Action dated 6/7/2005 (see pages 13-14).

Applicant contends that teaching of Sano et al. (EP 0797998 A1) is directed to the protection of endothelial cells. It is also asserted that one cannot extrapolate the results obtained in umbilical endothelial cells to other sources. Applicants also argue that there is no data presented from the endothelial cell culture. Applicants also contend that Sano et al. does not perform "administering to an individual" and assert that only *in vitro* data is presented. Applicant also requests the Office maintain the same standard with respect to enablement with respect to experimental support. Applicants' arguments have been fully considered but are not found to be persuasive. Contrary to the Applicants arguments the anti-inflammatory properties of IFN-β are inherent to this protein and thus are not dependent on the cells or diseases treated. Although Sano et al. may not have appreciated the full effect of IFN-β, the treatment itself nonetheless meets the limitations of the claim. Despite the fact that applicants may have been the first to characterize the effect of IFN-β in the treatment of hypoxia/ischemia related blood flow resistance that effect would inherently have occurred in the cells treated by Sano et al. The Examiner notes the decision in *Swinehart and Sfiligoj, 169 USPQ 226*, in which it was found that mere recitation of a newly discovered function or property, inherently possessed by things in prior art, does not cause claim drawn to those things to distinguish over prior art. Although the prior art did not necessarily appreciate the

mechanism by which the effect was attained, it clearly teaches the same method, using the same active agent, as the rejected claims. Furthermore, contrary to Applicants assertion that only *in vitro* methods are taught, Sano et al. contemplate the administration of the IFN orally or non-orally directly or in the form of pharmaceutical compositions to various diseases (see column 6, 7 and the claims).

Therefore, claims 1-11, 15-21 and 22-24 (newly added) remain rejected under 35 U.S.C 102(b) as being anticipated by Sano et al. (EP 0797998 A1)

Double Patenting, rejection maintained

10. The rejection of claims 1-11, 15-21 and 22-24 (newly added) remain provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-17 of copending Application No. 10/676, 847 for reasons of record in the Office Action of 6/7/2005. It is noted that Applicants have not responded to these rejections in the reply filed 10/14/2005.

11. No claims are allowable.

12. **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Contact information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jegatheesan Seharaseyon whose telephone number is 571-272-0892. The examiner can normally be reached on M-F: 8:30-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on 571-272-0961. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

JS 11/05

ROBERT S. LANDSMAN, PH D
PRIMARY EXAMINER